K112286

510(k) Summary

NOVAC 11

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

2.1. General Information

Submitter:
New Radiant Technology S.p.A.
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04011 - Aprilia (LT)
Italy

Establishment Registration Number: 3008058228

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Summary Preparation Date: July 30, 2011

2.2. Names

Device Name: NOVAC 11
Classification Name: Medical charged-particle radiation therapy system

Product Code: IYE
Regulation number: 892.5050

2.3. Predicate Devices

NOVAC 11 is substantially equivalent to the following devices:

Applicant	*Device name*	*510(k) Number*
Hytesis S.p.A.	NOVAC7	K990209
Intraop Medical Inc.	MOBETRON	K981112

NOVAC 11 and its predicate devices are electron linear accelerators used for radiation therapy (IORT) during surgical procedures in an operating room. They are used for the treatment of malignant and benign conditions.

NOVAC 11 and their predicate devices are also indicated for the same intended use and have the same operating principle (linear acceleration) and equivalent technical characteristics.

2.4. Device Description

The device is a linear electron accelerator for intra-operative treatments. Thanks to its construction characteristics, it can be used directly in the operating room.
NOVAC 11 is a reusable and non sterile electromedical device.

It is a mobile and articulated device. It can be moved towards the patient and put in the needed positions to carry out the necessary radiotherapy.

Radiation technique consists of administering a uniform and collimated dose of ionizing radiations to the tumor or other site. It is made through the surgical incision.

Collimation is performed by "Applicators" made of PMMA to minimize braking radiation.

Applicators are positioned according to the "Hard Docking" technique which ensures the maximum alignment accuracy, thus ensuring highly reproducible dosages.

The accelerator is equipped with an uninterruptible power supply which makes it completely independent during the radiation phase. Indeed, it ensures radiation continuity even if there are network power interruptions.

2.5. Indications for Use

The NOVAC 11 is an electron linear accelerator used for radiation therapy during surgical procedures in an operating room for the treatment of malignant and benign conditions. Known as Intraoperative Radiation Therapy (IORT), this technique allows delivery of high doses of radiation directly aimed at tumors or other sites while avoiding dosage to surgically mobilized normal tissues.

The NOVAC 11 is a mobile and articulated machine that can be moved towards the patient and put in the appropriate position to carry out the necessary radiotherapy. Applicators direct the electron beam to the surgical area of interest.

2.6. Performance Data

The New Radiant Technology S.p.A. NOVAC 11 device has been developed and tested according to the following international standards:

- IEC 60601-1 - Medical Electrical Equipment Part.1: General requirements for safety. 1: Collateral standard: safety requirements for Medical Electrical Systems.
- IEC 60601-1-2 Medical Electrical Equipment Part.1: General requirements for safety. 2- Collateral standard: electromagnetic compatibility – requirements and tests.
- IEC 60601-1-4 Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems.
- IEC 60601-2-1 Medical electrical equipment -- Part 2-1: Particular requirements for the safety of electron accelerators in the range of 1 MeV to 50 MeV.
- ISO 14971 Medical Devices - Application of risk management to medical devices.
- IEC EN 62304:2006 - Medical device software - Software life cycle processes.

Furthermore, New Radiant Technology has also used the guidance documents below:

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices – FDA – May 2005

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

New Radiant Technology S.p.A.
% Mr. Guido Bonapace
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APR 19 2012

Re: K112286
Trade/Device Name: NOVAC 11
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: April 10, 2012
Received: April 11, 2012

Dear Mr. Bonapace:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

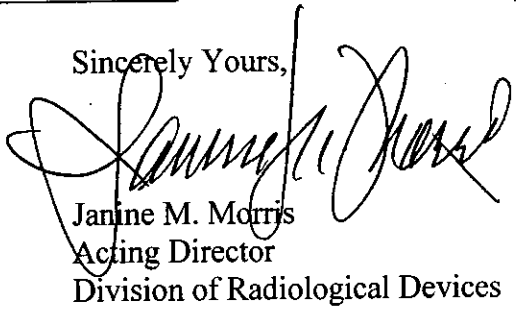
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112286

Device Name: **NOVAC 11**

Indications for Use:

The NOVAC 11 is an electron linear accelerator used for radiation therapy during surgical procedures in an operating room for the treatment of malignant and benign conditions. Known as Intraoperative Radiation Therapy (IORT), this technique allows delivery of high doses of radiation directly aimed at tumors or other sites while avoiding dosage to surgically mobilized normal tissues.
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Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___ ___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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